Supreme Court, U.S.
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No. 00-546

IN THE

Supreme Court of the United States

TORPHARM, INC.,

Petitioner,

v.

GENPHARM, INC., MYLAN LABORATORIES, INC., NOVOPHARM LTD., NOVOPHARM USA, INC., and GRANUTEC, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENTS GENPHARM, INC. and MYLAN LABORATORIES, INC.

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QUESTION PRESENTED

Petitioner seeks review of the decision by the Court of Appeals for the Federal Circuit affirming without opinion a district court decision that held invalid petitioner's patent. The district court held that patent invalid because it was undisputed that a third party commercially sold more than a quarter-ton of material covered by the patent three years before the patent application was filed. The only question presented is whether the Federal Circuit properly affirmed the district court's straightforward application of the statutory on-sale bar to the facts of this case using the test recently pronounced by this Court in *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998).

STATEMENT PURSUANT TO RULE 29.6

Pursuant to Rule 29.6 of the Rules of this Court, Counsel for the Respondents, Genpharm, Inc, and Mylan Laboratories, Inc., states that the identity of all parent corporations or publicly held companies that own 10 percent or more of the stock of either corporation's stock is as follows: Merck K.G.a.A. is the corporate parent of Genpharm.

Respondents Genpharm, Inc. and Mylan Laboratories, Inc., hereby oppose the Petition for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

REASONS FOR DENYING THE WRIT

I. THE DECISION BELOW PRESENTS NO ISSUE WARRANTING THIS COURT'S REVIEW

This case presents no issue worthy of review by the Supreme Court. The decision below does not conflict with the decision of any other court, involves no issues of constitutional law, and presents no important questions of federal law. An appellate court simply affirmed a district court's grant of summary judgment of patent invalidity based on undisputed facts and established legal standards.

The issues are so straightforward that the appellate court did not issue an opinion with its judgment, and there is no decision to cite as precedent. For the following reasons, petitioner TorPharm has failed to carry its heavy burden of establishing that the Supreme Court should review that decision.

A. The Federal Circuit Decision Will Not Affect Any Other Litigants

The Federal Circuit's affirmance of the district court's decision is not accompanied by an opinion, and there is therefore nothing to cite as precedent. The Federal Circuit's unanimous denials of petitions for rehearing and rehearing *en banc* also are not accompanied by opinion. No other litigant will be affected by these Federal Circuit decisions.

B. The Petition Presents No Conflict or Important Question of Federal Law

The Federal Circuit exercises exclusive jurisdiction over patent cases. As such, there exists no conflict between Circuit Courts of Appeals. Nor is there any conflict between any state courts of last resort and the Federal Circuit.

Petitioner attempts to contrive a conflict between the Federal Circuit's judgment without opinion and this Court's *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998) decision. Both the district court and the Federal Circuit decisions carefully followed this Court's decision in *Pfaff*.

In *Pfaff*, this Court clarified the law regarding the statutory on-sale bar of 35 U.S.C. § 102(b), which precludes a patent that covers any subject matter that was on sale more than one year before the filing date of the patent application. *Pfaff*, 525 U.S. at 67. This Court rejected the Federal Circuit's "totality of the circumstances" test for determining the trigger for the on-sale bar, in favor of a bright-line, two-part test. *Id.* at 66-68. This Court acknowledged that the Federal Circuit had criticized its own "totality of the circumstances" test as "unnecessarily vague." *Id.* at 66, n.11 (citing *Seal-Flex, Inc. v. Athletic Track and Court Constr.*, 98 F.3d 1318, 1323, n.2 (Fed. Cir. 1996)).

Under the two-part test announced in *Pfaff*, the on-sale bar precludes patentability when "the product [is] the subject of a commercial offer for sale . . . and the invention [is] ready for patenting." *Id.* at 67.

The sale that was the basis for the district court's ruling plainly meets the *Pfaff* test. *See* App. 8-12. The undisputed

facts show that Interchem Corporation, a United States supplier of pharmaceutical bulk raw material, made a commercial sale of over 600 pounds of the product at issue to Geneva Pharmaceuticals, Inc., an unrelated pharmaceutical company, several years before TorPharm's patent application was filed. App. 8-9, nn.4-5. The product was ready for patenting. App. 8-9. Petitioner essentially argues that this Court should undermine the bright-line approach it took in *Pfaff*, and create a fact-specific exception for this case. To suggest that fundamental legal principles should somehow be reworked to allow these facts to avoid the on-sale bar is without any merit.

TorPharm wrongly argues that an exception to the on-sale bar should be made because the sale was purportedly "secret." First, unlike the "public use" bar to patentability, the on-sale statutory bar does not require that the sale be "public." 35 U.S.C. § 102(b). Second, the sale was not "secret," because the purchaser and the seller knew about it. TorPharm's argument ignores over a century of established law that a use is public (and thus not secret) even if a single member of the public knows about it. *Egbert v. Lippman*, 104 U.S. 333, 336 (1881). Here, at least two major pharmaceutical companies, neither of which is even a party to this suit, participated in and were aware of the sale.

The district court opinion — the only opinion issued in this case — correctly noted that the pharmaceutical company that purchased the product was a member of the public, and cited the famous *Egbert* "corset case." App. 12. TorPharm's petition did not cite *Egbert*, and did not point out that the district court rejected TorPharm's "secrecy" contention that is now the premise for its petition. *See also Abbott Lab. v. Geneva Pharm., Inc.*, 182 F.3d 1315, 1317-19 (Fed. Cir.

1999) (holding that drug compound was "publicly sold" where transaction was made between third party pharmaceutical companies, not patentee).

The district court correctly and straightforwardly applied controlling Supreme Court precedent to the specific facts of this case. The Federal Circuit affirmed without opinion. Because there is no compelling reason for Supreme Court review of this case, this Court should deny certiorari.

CONCLUSION

For these reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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